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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,484	10/03/2003	Randall S. Hickle	82021-0048	4582

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HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER	
LOPEZ, AMADEUS SEBASTIAN	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/677,484	**Applicant(s)** HICKLE, RANDALL S.
	Examiner Amadeus S. Lopez	**Art Unit** 3771

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-13* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *03 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *2/25/04 & 12/6/04*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The examiner has considered all references disclosed within the Information Disclosure Statement filed on 2/25/04 and 12/06/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 7, and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Esteller et al (6594524).

As to claim 1, Esteller et al discloses a sedation and analgesia system, comprising: two or more patient health monitor devices (Col. 7, lines 28-35) adapted so as to be coupled to a patient and so as to each generate a separate input signal reflecting a parameter of a physiological condition of the patient (Col. 9, lines 34-35); a user interface (Col. 6, lines 31-36); a drug delivery controller (300) supplying one or more drugs to the patient (Col. 15, lines 6-32); and an electronic controller (300) interconnected with the patient health monitors, the user interface, and the drug delivery controller, wherein the electronic controller further comprises a threshold logic unit (Col. 10, line 37-67) which receives the input signals, multiplies each of the input signals by a predetermined weight corresponding to each of the parameters to achieve a weighted input signal for each corresponding input signal, combines the weighted input signals, and compares the weighted input signals against a predetermined threshold value to determine an action of the electronic controller (Col. 36, lines 41-67).

As to claim 2, Esteller et al discloses a sedation and analgesia system wherein the input signals are binary values (Col. 26, lines 9-40).

As to claim 3, Esteller et al discloses a sedation and analgesia system wherein each of the predetermined weights is trained to be set at a value representative of the significance of each signal resulting from the corresponding input and wherein the training comprises providing a series of inputs into the threshold logic unit indicative of at least one patient condition and the predetermined weights are adjusted until the system accurately detects adverse patient conditions and retains normal functionality during non-critical situations (Col. 6, lines 8-44; Col. 10, lines 16-36; Col. 14, lines 22-56).

As to claim 4, Esteller et al discloses a sedation and analgesia system wherein the action of the electronic controller comprises alarming clinicians (Col. 11, lines 9-25).

As to claim 6, Esteller et al discloses a sedation and analgesia system, comprising: two or more patient health monitor devices (Col. 7, lines 28-35) adapted so as to be coupled to a patient and so as to each generate a separate input signal reflecting a parameter of a physiological condition of the patient (Col. 9, lines 34-35); a user interface (Col. 6, lines 31-36); a drug delivery controller (300) supplying one or more drugs to the patient (Col. 15, lines 6-32); and an electronic controller (300) interconnected with the patient health monitors, the user interface, and the drug delivery controller, wherein the electronic controller further comprises a neural network to evaluate input signals to determine an action of the electronic controller (Fig. 32; Col. 10, line 37-67; Col. 36, lines 41-67) .

As to claim 7, Esteller et al discloses a sedation and analgesia system wherein the neural network comprises a set of inputs that make up a first layer of nodes, a set of hidden nodes, and a set of output nodes, wherein the inputs are related to any suitable feature of the patient health monitors (Fig. 32; Col. 36, line 30 to Col. 37, line 63).

As to claim 11, discloses a sedation and analgesia system wherein the input comprise heart rate (abstract).

As to claim 12, Esteller et al discloses a sedation and analgesia system wherein the action of the electronic controller (300) alarming clinicians (Col. 11, lines 9-25).

As to claim 13, Esteller et al discloses a sedation and analgesia system further comprising a radial basis function network (Col. 36, lines 41-50), wherein the at least one network increases the accuracy of sedation and analgesia system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller et al (6594524) in view of Burton (6431171).

As to claim 5, Esteller et al discloses a sedation and analgesia system with all the limitations within the claim with the exception of wherein the patient monitoring devices comprise at least two of a sensor monitoring nasal airway pressure, a sensor monitoring oral airway pressure, a sensor monitoring nasal capnometry, and a sensor monitoring oral capnometry. Burton discloses a system for controlling gas or drug delivery to a patient comprising several patient monitoring devices monitoring nasal and oral airway pressure and oral or nasal capnometry (Col. 1, line 45 to Col. 2, line 9). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sedation and analgesia system of Esteller et al to include oral and nasal pressure and capnometry monitoring systems as taught by Burton because it is well known in the art to monitor a patient's breathing pattern to verify that the patient is breathing properly and to alarm a clinician when the patient is not breathing properly which is usually indicative of a medical emergency so that proper treatment may be administered.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller et al (6594524) as applied to claim 7 above in view of Lapointe et al (6678669).

As to claim 8, Esteller et al discloses a sedation and analgesia system with all the limitations of the claim with the exception of wherein each of the input signals is weighted differently at each node to use parallelism of the neural network to accurately distinguish between normal and adverse patient conditions. Lapointe et al discloses a system for selecting a medical diagnostic test utilizing a neural network wherein each input signal into the neural network is weighted differently at each node to use parallelism (Col. 2, lines 21-52). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the neural network of Esteller et al to utilize parallelism as taught by Lapointe et al so that each of the inputs may be weighted differently because some inputs may be more indicative of a medical emergency than other inputs, which would make the system more effective and accurate in determining whether or not a medical emergency is likely to or has occurred so that clinicians may act accordingly and apply necessary treatment.

As to claim 9, Esteller et al discloses a sedation and analgesia system with all the limitations of the claim with the exception of wherein each input signal propagated to the hidden nodes is weighted by a numerical coefficient that indicates the significance of the respective parameter for the input signal. Lapointe et al discloses a system for selecting a medical diagnostic test utilizing a neural network wherein each input signal is weighted by a numerical coefficient that indicates the significance of the respective parameter for the input signal (Col. 2, lines 21-52). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neural network of Esteller et al to assign a numerical coefficient to each input signal as taught by Lapointe et al so that each of the inputs that are more indicative of a medical emergency are weighted differently making the system more effective and accurate in predicting whether a patient may need medical treatment so that they may be treated to either prevent a medical emergency or minimize damage to a patient's health.

As to claim 10, Esteller et al discloses a sedation and analgesia system with all the limitations of the claim with the exception of wherein the neural network adjusts its numerical coefficients through multiple iterations until it reduces its output error to a predefined acceptable range. Lapointe et al discloses a system for selecting a medical diagnostic test utilizing a neural network wherein the neural network adjusts its numerical coefficients through multiple iterations until it reduces its output error to an acceptable range (Col. 2, lines 21-52). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to "train" the neural network as disclosed by Esteller et al through multiple iterations as taught by Lapointe so that the neural network is more effective and accurate in determining whether or not a medical emergency is likely to or has occurred so that a patient may be treated as soon as possible to either prevent or minimize damage to a patient's health.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure to show patient monitoring systems that utilize neural networks: US 5251626 and US 6658396.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amadeus Lopez
Amadeus S Lopez
Examiner
Art Unit 3771
January 15, 2007

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
1/21/07